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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,678	05/15/1998	VERNON L. ALVAREZ	1101-220	8606

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EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/079,678

Applicant(s)

ALVAREZ ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75,109,110,117-128,135-142 and 149-165 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75,109,110,117-128,135-142 and 149-165 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This office action is in response to the amendment, received 1/13/05, in which applicant amended claim 75 and added new claims 156-165.

Claims 75, 109-110, 117-128, 135-142, and 149-165 are pending and will be examined as they read on SEQ ID NO: 51.

Claim Rejections - 35 USC § 112

Claims 75, 109, 127, 141, and 155 stand rejected under 35 USC 112, first paragraph for reasons of record which are restated below.

Claims 75, 109, 127, 141, and 155 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 51, a 44 amino acid sequence, does not reasonably provide enablement for 6 contiguous amino acids of the amino acid sequence of SEQ ID NO:51. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;

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- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to a method of delivering a drug to a subject comprising administering to the subject a therapeutically effective amount of a pharmaceutical composition comprising a therapeutically effective amount of a nucleic acid encoding a chimeric protein comprising a first protein comprising 6 contiguous amino acids of the amino acid sequence of SEQ ID NO: 51, said contiguous amino acids being capable of specifically binding to the gastro-intestinal receptor HPT1 (SEQ ID NO:178), said first protein being fused via a covalent bond to a second protein being a drug and a pharmaceutically acceptable carrier.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Others skilled in the art would be unable to practice the invention as claimed without undue experimentation of which 6 amino acids out of the 44 amino acids of SEQ ID NO:51 to use, with a reasonable expectation of success, other than using SEQ ID NO:51 itself.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 USC 112, first paragraph for the reasons set forth above.

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Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that it would be routine for the skilled artisan to identify any six contiguous amino acids from SEQ ID NO: 51 that would specifically bind to the HPT1 receptor given the teachings of the specification. The examiner contends that that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Others skilled in the art would be unable to practice the invention as claimed without undue experimentation of which 6 amino acids out of the 44 amino acids of SEQ ID NO:51 to use, with a reasonable expectation of success, other than using SEQ ID NO:51 itself.

New Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 156-165 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Further, 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention (including into the claim language). The material which is not supported by the original disclosure is as follows: In claims 156-165, the phrase "... sequence of

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SEQ ID NO: 51..." is deemed new matter because the instant specification does not properly support the concept of SEQ ID NO: 51 without the limitation in the non-cited claims that recites "...said contiguous amino acids being capable of specifically binding to the gastro-intestinal receptor HPT1 (SEQ ID NO: 178)..." Please note that the instantly claimed new matter reads upon numerous uses of SEQ ID NO:51 beyond the method of delivering a drug to a subject. However, the instant specification only teaches the delivery of a drug to a subject comprising administering SEQ ID NO:51, which is capable of specifically binding to the gastro-intestinal receptor HPT1 (SEQ ID NO: 178) It is suggested that the limitation set forth in the non-cited claims be appropriately incorporated into the claims cited above to overcome this rejection.

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHRISTOPHER R. TATE
PRIMARY EXAMINER